



UNITED STATES DEPARTMENT OF COMMERCE

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AS

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
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08/692,314 08/05/96 HAMLIN

R 910458, CDA

IM22/1105

EXAMINER

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DVE, R
ART UNIT

PAPER NUMBER

70

1772
DATE MAILED:

11/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

| | | | |
|------------------------------|-------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 08/692,314 | HAMLIN, ROBERT N. | |
| | Examiner Rena L. Dye | Art Unit 1772 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 13 August 2001.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 206-217 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 206-217 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892). | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u>69</u> |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Introduction

1. Claims 206-217 are currently pending in this application.

Withdrawn Rejections

2. The rejection of claims 206-217 under 35 USC §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as set forth in the last Office action (paper no. 66, paragraph no. 3), has been withdrawn upon further reconsideration.

Claim Rejections - 35 USC § 112

3. Claims 206-217 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the “Summary of the Invention” in the present specification, Applicant discloses that a tensile layer is combined as an outer layer with a chemically and physically compatible adhesion or bonding inner layer (page 2, last paragraph). Therefore, Applicant’s specification does not clearly support a layer of PEEK or PEK located as the inner layer, or a different polymeric layer as the outer layer. The PEEK or PEK layer should be claimed as the outer layer, or external to

the inner layer, and the second layer recited as the inner layer. Applicant's claims are recited more broadly than the present specification will support.

Response to Arguments

4. Applicant's arguments filed on August 13, 2001 have been fully considered but they are not persuasive.

Applicant's argument that the Examiner's reasoning limits Applicant to a preferred embodiment described in the specification, without considering the full teaching of the specification, is not convincing. The Examiner agrees that it is not necessary that the specification include a literal description of the invention, however, the present specification should certainly broadly disclose or teach one having ordinary skill in the art, at the time the application was filed, how to make the claimed invention. The present specification specifically discloses at page 2, line 20 through page 3, line 28 under the heading of "Summary of the Invention" that:

It has been found that a layer of medium or relatively high melt temperature material which also exhibits high tensile strength with relatively low distensibility be used to provide the required high burst or tensile strength and low radial expansion at high pressures required by the expander member in a composite structure....In the composite structure, the tensile layer is combined as an outer layer with a chemically and physically compatible adhesion or bonding inner layer which is fabricated from materials having superior glue bonding or melt bonding characteristics.....The bonding layer imparts the necessary adhesion properties to properly bond the expander member to the distal end portion of the catheter body (emphasis added). Examples

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of material exhibiting the required high tensile, low distensibility and having medium melt temperatures include ... polyetheretherketone (PEEK) and polyetherketone (PEK).

Therefore, it appears from Applicant's disclosure that a claim reciting an outer layer of PEEK or PEK layer (tensile layer) and a second inner layer (bonding layer) would be supported by Applicant's specification. The present specification would also support a PEEK or PEK layer which is external to the bonding layer. The specification, however, does not clearly support providing a PEEK or PEK layer as the inner layer, or a layer inside of the second layer or bonding layer, which would be included or encompassed by the undue breadth of the present claims. The specification specifically names PEEK and PEK as materials which exhibit the required high tensile strength and have medium melt temperatures. From this disclosure the PEEK or PEK layers would not provide the necessary bonding properties, *i.e.* lower melting point than the tensile layer (page 3, lines 4-6 of the spec.), to bond the expander member to the distal end of a catheter body.

The Examiner is not attempting to unduly limit Applicant's claimed invention to that which is a preferred embodiment. The Examiner is, however, attempting to limit Applicant's claimed invention to that which is clearly set forth as his invention at the time of filing, *i.e.* that which is broadly set forth at page 2, line 20 through page 3, line 28 of the present specification. The present disclosure does not clearly support the use of PEEK or PEK used in various layers with respect to the location of an inner or outer layer of the balloon catheter, or in any combination with respect to the second layer. It is the Examiner's position that one having ordinary skill in the art at the time of Applicant's invention would not have derived the claimed

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invention from the present disclosure. Accordingly, the rejection under 35 USC § 112, first paragraph, has been maintained as set forth above.

The rejection under 35 USC § 112, first paragraph (paragraph no. 3, paper no. 66) has been carefully reconsidered and withdrawn.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rena L. Dye whose telephone number is 703-308-4331. The examiner can normally be reached on Monday - Thursday 8:30 AM - 7:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon can be reached on 703-308-4251. The fax phone numbers for the

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organization where this application or proceeding is assigned are 703-305-5408 for regular communications and 703-305-3599 for After Final communications.

7. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



Rena L. Dye
Primary Examiner
Art Unit 1772

R. Dye
November 2, 2001